

### **REMARKS**

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 1, 3, 7-12 and 38 are pending and under examination, with claim 1 being in independent format.

The specification has been amended to remove hyperlinks. Claims 5 and 25 have been cancelled, and claim 38 has been added. Claim 1 has been amended to include the subject matter recited in cancelled claims 5 and 25. Claim 10 has been amended to correct a minor typographical error, and withdrawn claim 26 has been amended to mirror the language of amended claim 1. Newly added claim 38 depends from claim 1 and mirrors the language of withdrawn claim 28.

It is urged that support for all the above amendments may be found throughout the specification as originally filed, and that none of the amendments constitute new matter or raise new issues for consideration. Applicants specifically reserve the right to pursue claims to any subject matter that may have been cancelled from the claims by the above amendments in one or more related patent applications.

### **Objections to the Specification**

The Examiner objected to the disclosure as containing hyperlinks. This has been corrected.

### **Claim rejections under 35 USC §103(a)**

Claims 1, 3-5, 7 and 25 stand finally rejected under 35 USC §103(a) as being unpatentable over US Patent 5,482,560 to Ammeraal et al. ("Ammeraal et al."). Applicants note that claim 4 was cancelled in the Amendment and Reply filed on June 21, 2010, and that claims 5 and 25 have been cancelled by the above amendments. The rejection of claims 1, 3 and 7 is respectfully traversed.

Following the above amendments, independent claim 1 is drawn to a bioadhesive formulation comprising an active agent and a mucoadhesive carrier for the active agent, wherein the mucoadhesive carrier comprises a  $\beta$ -limit dextrin that is obtained by hydrolyzing a waxy starch, and the formulation is a buccal melt product comprising a freeze-dried matrix, wherein the buccal melt product is a wafer. Applicants note that claims 3 and 7 depend from claim 1 and

therefore encompass all the limitations of claim 1. As discussed in paragraphs 0024-0026 of the published application, the claimed formulations are effective in rapidly delivering active agents to a mucosal membrane, for example in the buccal cavity of a subject.

Ammeraal et al. teach beta-limit dextrins (BLDs) prepared from *dull* waxy starch and their use in foods and beverages as, for example, a flavor carrying agent, beverage clouding agent. The reference teaches that the BLDs from dull waxy starch are soluble and more stable in aqueous solutions than conventional BLDs (see abstract), but also states that “they can function as slow release agents in appropriate applications” (col. 1, lines 63-67). Examples 1 and 3 of Ammeraal et al. describe studies demonstrating that the molecular weight of BLDs prepared from dull waxy starch are significantly different to those of BLDs from waxy starch, while Example 4 of Ammeraal et al. describes studies demonstrating that the BLDs from dully waxy starch have “superior ability ... to act as a carrier” compared to BLDs from waxy starch. Furthermore, as evidenced by Fuwa et al. (Starch 39:295-298 (1987); copy submitted herewith for the Examiner’s convenience), it is known in the art that the amylopectin present in dull waxy starches has a different structure to that found in waxy starches. Thus, BLDs from dull waxy starch are not the same as, and have different properties to, BLDs from waxy starch. Applicants have been unable to find any teaching or suggestion in Ammeraal et al. of BLDs obtained from a waxy starch as recited in amended independent claim 1.

Ammeraal et al. do not teach or suggest the use of BLDs as mucoadhesive carriers, nor do they disclose or suggest a formulation including a BLD wherein the formulation is a buccal melt produce comprising a freeze-dried matrix, wherein the buccal melt product is a wafer, as recited in amended claim 1. Furthermore, while Ammeraal et al. include freeze-drying in a list of possible methods for recovering BLDs prepared from dull waxy starch (see, col. 2, lines 58-61), the reference does not teach or suggest the use of freeze-drying in the preparation of a formulation including the BLD.

It is urged that Ammeraal et al. would not have rendered the presently claimed subject matter obvious to one of skill in the art at the time the invention was made and that the rejection of claims 1, 3 and 7 under 35 USC §103(a) can thus be properly withdrawn.

Claims 1 and 8-12 stand finally rejected under 35 USC §103(a) as being unpatentable over US Patent 4,748,032 to Kono et al. (“Kono et al.”). This rejection is respectfully traversed.

As discussed above, amended independent claim 1 is drawn to a bioadhesive formulation comprising an active agent and a mucoadhesive carrier for the active agent, wherein the mucoadhesive carrier comprises a  $\beta$ -limit dextrin that is obtained by hydrolyzing a waxy starch, and the formulation is a buccal melt product comprising a freeze-dried matrix, wherein the buccal melt product is a wafer.

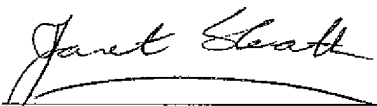
Kono et al. describe a method for preventing deterioration of food by adding oligosaccharides prepared from agar and/or carrageenan. At col. 3, lines 59-67, the reference states that the oligosaccharides can be used in combination with a conventional carbohydrate, such as BLD and/or sodium alginate. Applicants have been unable to find any teaching or suggestion in Kono et al. of a mucoadhesive carrier comprising any type of BLD, let alone a BLD that is obtained from a waxy starch, as recited in amended independent claim 1. Nor do Kono et al. teach or suggest a formulation comprising an active agent and such a mucoadhesive carrier wherein the formulation is a buccal melt product comprising a freeze-dried matrix, and the buccal melt product is a wafer as recited in claim 1. Claims 8-12 depend from independent claim 1 and thus encompass all the limitations of claim 1.

It is urged that Kono et al. would not have rendered the presently claimed subject matter obvious to one of skill in the art at the time the present invention was made, and that the rejection of claims 1 and 8-12 under 35 USC §103(a) can thus be properly withdrawn.

#### **Concluding Remarks**

Every effort has been made to put the claims in condition for allowance. Early reconsideration and allowance of the amended claims is respectfully requested. Should the Examiner have any questions or concerns regarding the application, he is respectfully requested to telephone the undersigned at (206) 382.1191.

Respectfully submitted,

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